

Endo-RS[®]

Endotoxin Recovery Kit (Surfactant)

Toolbox for demasking endotoxin in biopharmaceutical formulations containing surface active agents

Endo-RS[®] Endotoxin Recovery Kit is a novel sample preparation kit enabling complete endotoxin recovery in biopharmaceutical drug formulations containing non-ionic surfactants such as Polysorbate 20, Polysorbate 80 or Octylphenol ethoxylates.

Non-ionic surfactants are well known to cause Low Endotoxin Recovery (LER). Intensive studies of the phenomenon have shown that the physicochemical properties of surfactants render endotoxin molecules inaccessible (masked) for detection in such samples. The **Endo-RS[®]** Endotoxin Recovery Kit now provides the essential reagents and a detailed guideline for evaluating and establishing an optimized endotoxin demasking protocol for each individual formulation containing surfactants.

Applying the **Endo-RS[®]** Endotoxin Recovery Kit prior to endotoxin detection with the **EndoLISA[®]** Endotoxin Detection Assay will ensure FDA-compliant and accurate results in spike validation studies¹ and routine quality control testing.



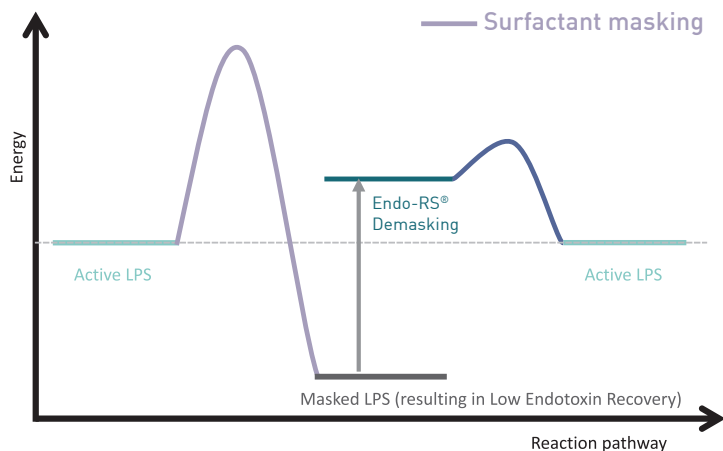
Endo-RS[®] benefits

- Full quantitative endotoxin recovery in biopharmaceutical samples containing surfactants
- Demasking independent of masking time and endotoxin concentration
- All needed reagents for developing a formulation-specific protocol included in the kit
- Detailed technical guidelines provided

¹ In order to verify the reliability of the endotoxin assay, time-dependent endotoxin spiking studies with undiluted drug product lots are required by the FDA. The drug product lots are spiked with specified endotoxin levels, and held for several days (depending on matrix) before being assayed.

Endo-RS[®] work principle

Rearrangement of Endotoxin (LPS) into Factor C active state (Reich et al. 2014):



Procedure for establishing a routine test protocol with Endo-RS[®]:

- 1. Screening**
Selection of the agents suitable for the specific formulation
- 2. Optimization**
Adjustment of protocol
- 3. Detection**
Quantification of demasked (accessible) endotoxin with the EndoLISA[®] assay

Endo-RS[®], Cat. No. 609065, included in the delivery:

Reagent	Function
Buffer	Buffer for pH adjustment of samples
Disturber	Destabilizing the LPS-Masker-Complex
Adsorber	Adsorption of surfactant
Modulator 1	Supporting Reconfigurator
Modulator 2	Supporting Reconfigurator
Reconfigurator	Enabling the formation of detectable LPS aggregates
Endotoxin	LPS from <i>E. coli</i> 055:B5, lyophilized, matrix-free
Water	Endotoxin-free water for reconstitution of endotoxin and adsorber as well as for dilution of components and samples

Find out more on www.biovendor.com

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